510(k) SUMMARY

K053092

AUG 0 1 2006

A. Submitter Information:

Submitter:	MEDCOMP® 1499 Delp Drive Harleysville, PA 19438 (215) 256-4201 Telephone (215) 256-9191 Fax
Contact:	Jean Callow Regulatory Specialist
Date Prepared:	October 25, 2005

B. Trade Name: Vascu-Sheath® II

Common Name:	Introducer, Catheter
Classification:	DYB
C.F.R. Section:	870.1340

C. Predicate Device:

K993191 TFX Medical Introducer Assembly
K022513 Medcomp Vascu-Sheath® Introducer Set

D. Device Description:

The Medcomp Vascu-Sheath® II is a two-part single use device used to obtain vascular access and facilitate intravascular catheter insertion. The Medcomp Vascu-Sheath® II consists of a peel-able introducer sheath and vessel dilator. The dilator is comprised of a cylindrical tube with a hub; the sheath is also a cylindrical tube with a hub. The dilator extends beyond the sheath to provide a zero tolerance clearance between sheath and dilator. The device is available in three dilator lengths, 5cm, 10cm and 13.5cm and a range of French sizes from 5F thru 7F for the 5 and 10cm lengths and 5F thru 18F for the 10cm length. The sheath and dilator when used in conjunction with an introducer needle and guidewire provide a means to obtain a percutaneous opening to the vascular system to facilitate the insertion of a catheter. After removing the dilator a catheter can then be placed through the sheath. Breaking the sheaths hub and peeling the sheath away from the catheter then allows the sheath to be removed. The dilator is composed of a High Density Polyethylene with Barium Sulfate in the dilator for visibility under fluoroscopy by the attending physician during insertion. The sheath is composed of PTFE to provide a smooth, consistent peel.

E. Intended Use:

Vascu-Sheath® II introducers are intended to obtain central venous access to facilitate catheter insertion into the central venous system.

F. Comparison to Predicate Device:

The technological characteristics of the Vascu-Sheath® II are substantially equivalent to the predicate devices in terms of intended use, design, material type, performance, and method of sterilization.

G. Performance Data:

In Vitro performance data for the Medcomp Vascu-Sheath® II, including peel force, demonstrates that this device is substantially equivalent to the legally marketed device.

Clinical studies were not deemed necessary since in-vitro testing was sufficient to demonstrate safety and effectiveness by way of comparison to the legally marketed predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 0 1 2006

Medcomp
c/o Ms. Jean Callow
Regulatory Specialist
1499 Dale Drive
Harleysville, PA 19438

Re: K053092
Vascu-Sheath® II
Regulation Number: 21 CFR 870.1340
Regulation Name: Catheter Introducer
Regulatory Class: II
Product Code: DYB
Dated: June 29, 2006
Received: June 30, 2006

Dear Ms. Callow:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): __053092________

Device Name: ___Medcomp ® Vascu-Sheath® II_____________________________

Indications for Use:

VASCU-SHEATH II® II INTRODUCERS ARE INTENDED TO OBTAIN CENTRAL VENOUS ACCESS TO FACILITATE CATHETER INSERTION INTO THE CENTRAL VENOUS SYSTEM.

Prescription Use __X_____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _______ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Cardiovascular Devices

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